REMARKS

This is a full and timely response to the Final Office Action mailed September 10, 2008. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

A. Present Status of Patent Application

Claim 104 has been amended merely to improve clarity. Claims 42 and 106 are cancelled hereby, without prejudice, waiver or estoppel. Claims 23-37 and 84-102 had been previously withdrawn pursuant to a Restriction Requirement.

Claims 38-39, 41, 44, 47-56, 58, 60, 62-68, and 103-105 remain pending.

B. Response to Rejections

1. Provisional Double Patenting Rejection

Applicant again notes the rejection of claims 1-8, 12-15, 19, 20, 38-44, 46-49, 52, 69-75, 77-79, and 82 on the ground of nonstatutory obviousness-type double patenting over the claims of co-pending U.S. application 11/187,757, and again notes the **provisional** status of the rejection. To the extent the provisional rejection matures into a double-patenting rejection which is the sole ground of rejecting the present claims, consideration will be given to filing an appropriate terminal disclaimer.

2. Rejection under 35 U.S.C. §112, Second Paragraph

Claims 104 and 105 were rejected under 35 U.S.C. §112 (second paragraph) as allegedly indefinite with respect to the term 'low". The rejection is respectfully traversed for the following reasons. A relative term, such as "low" is not indefinite *per se*. See Exxon Research and Engineering Co v. United States (CAFC 2000) 54 PQ2d 1519; Hybritech Inc, v. Monoclonal Antibodies, Inc. (CAFC 1986) 231 USPQ 81. However, solely to expedite prosecution, and without conceding the definiteness *vel non* of the term "low", applicants have amended claim 104 to incorporate the limitation of a temperature below about 283°C as recited in claim 106, now cancelled.

3. Rejection under 35 U.S.C. §103(a)

Claims 38, 39, 41, 42, 44, 47-58, 60, 62-68 and 103 were again rejected under 35 USC §103(a) over *Weers et al.* WO 01/85136 or US 2002/0037316. New claims 104-106 were also rejected under 35 USC §103(a) over *Weers et al.* WO 01/85136 or US 2002/0037316. These rejections are traversed as to the pending claims.

Initially, it should be noted that the Examiner has relied on a single reference as the basis for rejecting applicants' claims under §103(a). When a single reference is presented to support an obviousness rejection, the Examiner must cite evidence of general knowledge in the art that, together with the reference, makes a case for obviousness, or must submit – in the form of an affidavit – Examiner's own knowledge of facts that combine with the reference to make the claimed invention obvious. See 37 CFR §1.104(d)(2); MPEP 2112(IV). The evidence must be "clear and particular." In re Dembiczak. Importantly, since an Examiner is, under the law, not considered one skilled in the art, the Examiner's opinion as to what one skilled in the art may (or may not) choose to do with the composition of Weers (e.g., formulating an insoluble active agent to comprise a porous particle suitable for pulmonary delivery) is of no moment. In re Rijckaert ("[T]he examiner's assumptions do not constitute the disclosure of the prior art"). If the Examiner has knowledge of facts relevant to any of the pending rejections, the Examiner may file an affidavit to make those facts of record in the prosecution. The Examiner has submitted no such affidavit. Instead, the Examiner provides only an opinion. The Examiner's statements do not qualify as the requisite "evidence" needed to support an obviousness rejection. Therefore, for at least the foregoing reasons, applicants respectfully request the pending rejection under 35 U.S.C. §103 be withdrawn.

With the above legal standard in mind, it is apparent that Weers et al., while mentioning the possibility of formulating **insoluble** active agents, does not provide any teaching or guidance as to how to do so (apart from suggesting that they be dispersed in an emulsion). More specifically, Weers does not teach, suggest or disclose a particulate engineered for pulmonary administration wherein the particulate is formed of an active agent having a low solubility defined as being between about 0.1 to about 1.0

mg/mL. Nor does Weers et al. teach a particulate engineered for pulmonary administration wherein the particulate comprises an insoluble particle having a geometric diameter of less than about 3 microns and dispersed within a phospholipids matrix. Indeed, Weers et al **can not** teach or suggest such a claim limitation as of Weers et al does not relate to incorporation of discrete insoluble particles in a matrix. Instead Weers et al. teaches:

> In any event, the use of these and substantially equivalent methods provide for the formation of hollow porous aerodynamically light microparticles with particle diameters appropriate for aerosol deposition into the lung. microstructures that are **both hollow and porous, almost honeycombed or foam-like in appearance**. In especially preferred embodiments the particulate compositions comprise hollow, porous spray dried microparticles. *[emphasis added]*

Weers et al. at Paragraph 0065

Moreover, and as previously noted *Weers et al* is directed generally to a different type of composition, *to wit* a soluble or relatively soluble particulate formulation which is formulated from a solution of soluble particle and the lipid. The particulate is engineered to be hollow and porous, and generally consistent and uniform about any cross section.

Further, as applied to claims 104 and 105 of Weers et al does not teach or suggest a particulate engineered for pulmonary delivery, comprising an active agent particle having a geometric diameter of less than about 3 μm and at least one property of a solubility in water of about 0.1 to about 1.0 mg/ml, or a low glass transition temperature (T_g) which comprises about 283°C, and a porous phospholipid matrix material.

Weers et al. does refer, in Example V, to powders which incorporate poorly soluble actives, but *Weers et al.* does not specifically teach or suggest the claimed compositions, and methods of making, comprising porous particulates **consisting essentially** of active agent particles in a matrix comprising a phospholipid, the active agent particles having a geometric diameter of less than about 3 μm and **a solubility in water of about 0.1 to about 1.0 mg/ml** and wherein the active agent particles are dispersed within the phospholipid matrix. Example V of *Weers et al.* incorporates an

excipient (lactose monohydrate) thus teaching the opposite of the invention claimed by the applicants.

As the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of independent claims 38, 54 and 104, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

In view of the above, applicants respectfully request that these grounds of rejection be withdrawn.

Conclusion

In view of the foregoing, applicants submit that pending claims 38-39, 41, 44, 47-56, 58, 60, 62-68, and 103-105 satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 283-6790.

Respectfully submitted,
Nektar Therapeutics

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